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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PREBILIC, PAUL B	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No.	Applicant(s)	
	09/289,000	BLATT, GERALD	
	Examiner	Art Unit	
	Paul B. Prebilic	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 24-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On line 5 of claim 26, the step of "covering the bone surface with a layer of at least one blood and hematoma" lacks original support because the original specification does not support a positive act of putting a blood or hematoma on the bone surface; see page 3, lines 22-26 of the specification. Rather, the process of blood clot or hematoma formation occurs naturally to the resected bone surface; see *supra*. For this reason, the claim language lacks original support and constitutes new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, on line 5, claim 24, on lines 5-6, line 12, and lines 13-14, claim 25, on line 5, and claim 26, on line 6, the Markush language of "a layer of at least one of blood and hematoma" is improper because it is

not clearly a closed listing; see MPEP 2173.05(h). The Examiner suggests inserting "selected from the group consisting" after "layer" in order to overcome this objection.

Claim Objections

Claims 1-6 and 24-26 are objected to because of the following informalities:

In claim 1, on line 5, claim 24, on lines 5-6, line 12, and lines 13-14, claim 25, on line 5, and claim 26, on line 6, the Markush language of "a layer of at least one of blood and hematoma" does not have clear antecedent basis from the specification because "blood clot" not "blood" is used therein. The Examiner suggests changing "blood" to "blood clot" in order to overcome this objection.

As an alternative to the Section 112, first paragraph rejection given above, in claim 26, on line 5, it may be that the word "and covering the bone surface" was inadvertently used instead of "covered" as in the three other independent claims. For this reason, the Examiner will interpret the claim language as "covered" when evaluating claim 26 on its merits. Claim 26 would be allowable if interpreted as claiming a positive step of placing an exogenous blood clot or hematoma on the surface of the exposed cancellous bone. Applicant would have to amend claim 26 to make this fact clear, though, by inserting a term such as "exogenous" before "blood." Such a change would not automatically overcome the Section 112, first paragraph rejection where convincing proof of original support would have to be provided.

Appropriate correction is required.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-6, and 24-26 are rejected under 35 U.S.C. 102(b) as anticipated by Stone et al (US 5,306,311) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stone et al (US 5,306,311) in view of Cohen (US 5,207,712). Stone anticipates the claim language where removing the joint surface to expose cancellous bone is disclosed by Stone on column 5, line 58 to column 6, line 2 and on column 15, lines 35-50, the selecting implant step is disclosed by Stone on column 3, lines 3-10, the placing step is shown in Figure 9 and discussed on column 2, lines 49-61 (the cancellous bone is element (450)), the using step is explained in the previous citations of Stone, and the allowing step naturally occurs in the 3 to 6 months that the implant is in place; see Example 14 on column 15.

As is clear from the disclosure on page 3, lines 22-26, the blood clot or hematoma normally naturally forms on the exposed bone surface. For this reason, such blood clot or hematoma would inherently form on the Stone exposed surface because the same bone surface is being exposed in the same manner as that of Applicant.

Stone discloses that "a **resorbable prosthesis** which acts as a **temporary** in vivo scaffold for articular chondrocyte infiltration and cartilage regeneration" is provided; see column 2, lines 55-57. The base component of Stone "may be nonresorbable, partially resorbable or totally resorbable" (see column 4, lines 1-2), and the matrix "establishes a bioresorbable scaffold adapted for ingrowth" (see column 3, lines 17-18) where "any biocompatible, bioresorbable fibers" can be used (see column 6, lines 17-20). For these reasons, the Examiner asserts that Stone at least discloses an embodiment where the implant is completely resorbable as claimed.

Alternatively, one may not consider Stone as disclosing a completely resorbable embodiment because the matrix and the base are disclosed as possibly being made partially or entirely with non-bioresorbable materials. However, Cohen teaches that it was known to make similar implants out of completely resorbable materials; see the abstract. For this reason, it is the Examiner's position that it would have been obvious to make the Stone invention entirely out of resorbable materials for the same reasons that Cohen does the same and in order to avoid the development of long term immune response conditions.

With regard to claim 1 specifically, line 9-10, the slidable contact of the implant with the bone surface is considered inherent for the same reason that such contact is

present in Applicant's surface; i.e. the same implant structure as claimed must have motion as Stone because it is the same structure. Furthermore, the Examiner reasons that the Stone implant would inherently be able to rotate about its central axis while within the bone cavity because the threads thereon can be concentric or helical and self-tapping; see column 6, lines 3-16.

With regard to claims 4 and 25, Stone fails to disclose estimating the time of healing and selecting an implant of the size, shape and material for that period of time. However, the Examiner asserts that it would have been obvious to perform these steps to an ordinary artisan in order to ensure the greatest success with the procedure.

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al (US 5,306,311) and Cohen, as applied in the rejection of claims 1, 4-6 and 24-26, further in view of Athanasiou et al (US 5,607,474). Stone discloses using a wide variety of resorbable materials as the bioresorbable component, but fails to disclose using a lactic acid copolymer as claimed; see column 3, lines 39-46 and column 6, lines 18-55. However, Athanasiou teaches that it was known to make similar joint implants out of lactic acid copolymers; see Figures 2 and 3 as well as column 3, lines 35-59 and column 5, lines 24-45. Therefore, it is the Examiner position that it would have been prima fascia obvious to replace some of the resorbable materials of Athanasiou with lactic acid copolymers in order to reduce the cost and antigenicity of the device as compared to using collagen.

Response to Arguments

Applicant's arguments filed January 3, 2005 have been fully considered but they are not persuasive.

Applicant argues that Stone is distinct from the presently claimed invention because he argues that Stone discloses an implant that is at least partially non-resorbable. However, the Examiner posits that Stone does disclose an embodiment where the implant is entirely resorbable. At the minimum, Stone suggests making the implant entirely out of resorbable material. Applicant is directed to the rejections above that detail where this embodiment or suggestion to do the same is disclosed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Prebilic
Primary Examiner
Art Unit 3738